REMARKS

Claims 1-14, 16, and 18-27 remain in the application. Claims 1, 5, 7-9, 13, 14, 18, 20-22, and 27 have been amended. Claims 15 and 17 have been canceled. A new drawing has been added. Minor amendments have been made to the specification. Reconsideration of this application, as amended, is respectfully requested.

Claim 1 has been amended to specify that the biosensor strip is for determining the concentration of an analyte in a sample of biological liquid. Support for this amendment can be found at page 5, lines 16-18 of the specification. Claim 1 has been further amended to specify that the working ink comprises (i) a reagent responsive to the analyte in the sample of the biological liquid and (ii) an electron mediator deposited on an electrically conductive material. Support for this amendment can be found at page 8, lines 7-29 of the specification.

Claim 13 has been amended to specify that the biological fluid is a biological liquid. Support for this amendment can be found at page 17, lines 15-18 of the specification.

Claim 14 has been amended to specify that the biosensor strip is for determining the concentration of an analyte in a sample of biological liquid. Support for this amendment can be found at page 5, lines 16-18, of the specification. Claim 14 has been further amended to specify that the working ink comprises (i) a reagent responsive to the analyte in the sample of the biological liquid and (ii) an electron mediator deposited on an electrically conductive material. Support for this amendment can be found at page 8, lines 7-29 of the specification. Claim 14 has been further amended to specify that the reference electrode comprises (i) a reagent responsive to the analyte in the sample of the biological liquid and (ii) an electron mediator deposited on an electrically conductive material. Support for this amendment can be found at page 9, lines 25-30 of the specification and in claim 17, as originally filed. Claim 14 has been

further amended to change "second electrode support" to "cover layer" and to place the proper letter before the appropriate component.

Claim 27 has been amended to specify that the biological fluid is a biological liquid. Support for this amendment can be found at page 17, lines 15-18 of the specification.

Claims 5 and 18 have been amended to specify that the reagent responsive to the analyte in the sample of the biological liquid is an enzyme. Claims 5 and 18 have been further amended to remove the redundant mention of the electron mediator, which is mentioned in claims 1 and 14, respectively.

Claims 7-9 have been amended to depend from and conform to claim 1, and claims 20-22 have been amended to depend from and conform to claim 14.

A new drawing has been added to illustrate another embodiment of the invention. Support for this drawing can be found at page 16, lines 10-16 of the specification.

The specification has been amended to account for the new drawing. The specification has been further amended to correct a typographical error.

The drawings were objected to under 37 CFR 1.83(a). A new drawing, FIG. 9, has been added to address this objection.

Claim 14 was objected to for informalities. Claim 14 has been amended to address this objection.

Claims 14-26 were rejected under 35 U. S. C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection has been addressed by the changing of "second electrode support" to "cover layer" and the relettering of the clauses of claim 14.

Claims 1-3, 10, 11, and 13 were rejected under 35 U. S. C. §102(b) as being anticipated by Maley et al. (US 5,494,562). This rejection is respectfully traversed in view of the amendments to claim 1.

Maley et al., U. S. Patent No. 5,494,562 (hereinafter "Maley et al."), discloses a solid state, multi-use electrochemical sensor having an electrically, nonconductive substrate, a working electrode, and a semi-

permeable membrane covering the working electrode. The working electrode includes an electrically conductive material adhered to a portion of the substrate. A first portion of the conductive material is covered with an electrically insulating dielectric coating, and a second portion of the conductive material is covered with an active layer. The active layer includes a catalytically active quantity of an enzyme carried by platinized carbon powder particles, which are distributed throughout the active layer.

Maley et al. discloses an electrochemical sensor for repeated measurement of glucose or lactate in a device such as a laboratory analyzer. The sensor has a semi-permeable membrane that allows the permeation of only oxygen and the analyte of interest, and the enzyme is positioned over the working electrode. Maley et al. discloses the measurement of hydrogen peroxide. The sensor in Maley et al. does **not** employ an electron mediator. In contrast to Maley et al., the biosensor of the present invention employs a working electrode that comprises an electron mediator. For this reason, Maley et al. does not anticipate claims 1-3, 10, 11, and 13 of this application.

Claims 1-3, 5, 10, 11, and 13 were rejected under 35 U. S. C. §102(b) as being anticipated by Park et al. (US 5,571,395). This rejection is respectfully traversed in view of the amendments to claim 1.

Park et al., U. S. Patent No. 5,571,395 (hereinafter "Park et al."), discloses a biosensor for measuring alcohol concentration including an insulating substrate and an amperometric device formed on the insulation substrate, having a plurality of conductive lines and connective pads and a plurality of electrodes. An enzyme-immobilized layer is formed on one of the plurality of electrodes of the amperometric device and an enzyme paste is printed on the amperometric device. An outer membrane is formed on the substrate having the plurality of electrodes for forming an electrode system and an insulating membrane is formed on the substrate, except on the outer membrane.

Park et al. discloses a biosensor having a working electrode, a counter electrode, and a reference electrode for the determination of the concentration of analytes in a vapor phase (e.g., alcohol in breath). The biosensor in Park et al. does **not** disclose the use of an electron mediator in combination with a

biosensor employing a working electrode, a reference electrode, and a counter electrode for the determination of the concentration of analytes in a liquid phase (e.g., glucose in blood). In contrast to Park et al., the biosensor claimed in the present invention requires a working electrode, a reference electrode, and a counter electrode, and further requires an electron mediator associated with the working electrode, and further requires that the sample be in the liquid phase. For these reasons, Park et al. does not anticipate claims 1-3, 5, 10, 11, and 13.

Claims 1-3, 5, 10, 12, and 13 were rejected under 35 U. S. C. §102(b) as being anticipated by Yee (US 5,672,256). This rejection is respectfully traversed in view of the amendments to claim 1.

Yee, U. S. Patent No. 5,672,256 (hereinafter "Yee"), discloses a multi-electrode biosensor for sensing a material present in a sample including a substrate, a plurality of working electrodes formed on the substrate, a counter electrode formed on the substrate, and a reference electrode formed on the substrate.

Yee discloses a biosensor for the determination of the concentration of alcohol in a vapor. The sensor contains multiple working electrodes, a counter electrode, and a reference electrode. An outer cellulose layer is deposited on the electrodes to trap alcohol vapors. The biosensor disclosed in Yee does **not** have an electron mediator associated with the working electrode. In contrast to Yee, the claims of the present application require a reagent responsive to the analyte in the sample of the biological liquid. In further contrast to Yee, the claims of the present application require an electron mediator associated with the working electrode. For these reasons, Yee does not anticipate claims 1-3, 5, 10, 12, and 13.

Claims 1-3, 10, 11, and 13 were rejected under 35 U. S. C. §102(e) as being anticipated by Fujiwara et al. (US 6,309,526 B1). This rejection is respectfully traversed for the following reasons.

Fujiwara et al., U. S. Patent No. 6,309,526 B1 (hereinafter "Fujiwara et al."), discloses a biosensor that is fabricated by forming a metal film over the surface of a substrate through evaporation, sputtering or by gluing a metal foil, then splitting the metal film into three regions, and forming a reagent layer on an area of measuring electrode and two counter-electrodes for placing a

liquid sample on by providing a cover disposed over the split metal film. The electrodes can be formed without dispersion.

Fujiwara et al. discloses a biosensor formed by metal electrodes containing an enzyme and mediator (ferricyanide) deposited on the active area. The electrodes in the biosensor function as a working electrode and a counter electrode. The two electrodes along the sides in the biosensor function as counter electrodes. Fujiwara et al. does **not** disclose an electrode that functions as a reference electrode. For this reason, Fujiwara et al. fails to anticipate claims 1-3, 10, 11, and 13.

Claims 1-8 and 10 were rejected under 35 U. S. C. §102(e) as being anticipated by Winarta et al. (US 6,287,451 B1). This rejection is respectfully traversed for the following reasons.

Winarta et al., U. S. Patent No. 6,287,451 B1 (hereinafter "Winarta et al."), discloses a disposable electrode strip for testing a fluid sample including a laminated strip with a first and second end, a reference electrode embedded in the laminated strip proximate to the first end, at least two working electrodes embedded in the laminated strip proximate to the first end and the reference electrode, an open path for receiving a fluid sample beginning from the first end and being sufficiently long to expose the reference electrode and the working electrodes to the fluid sample, and conductive contacts located at the second end of the laminated strip. The laminated strip has a base layer with a conductive coating, a reagent-holding layer, a channel forming layer and a cover. One of the working electrodes contains a reagent substantially similar to the reagent of the reference electrode and a second working electrode contains a reagent having an enzyme.

Winarta et al. discloses a biosensor having three electrodes where two of the three electrodes function as working electrodes while the third electrode functions as a reference electrode. The second working electrode is used to determine the background signal to compensate for solution variables such as hematocrit. In other words, the second working electrode functions as a dummy electrode. Winarta et al. does **not** disclose an electrode that functions as a

counter electrode. For this reason, Winarta et al. does not anticipate claims 1-8 and 10.

Claims 1-6 and 9-12 were rejected under 35 U. S. C. §102(b) as being anticipated by Forrow et al. (WO 99/19507). This rejection is respectfully traversed for the following reasons.

Forrow et al., WO 99/19507 (hereinafter "Forrow et al."), discloses an amperometric dry-strip sensor that includes an elongated, electrically insulating carrier having a pair of longitudinal, substantially parallel electrically conducting tracks thereon, and a pair of electrodes. The electrodes can each be electrically connected to a different one of the tracks; one of the electrodes can be a reference/counter electrode, while another electrode can be a working electrode. The third electrode is a fill indicator electrode. The sensor can also include a dummy electrode.

Forrow et al. discloses the use of phenanthroline quinone mediators for NAD(P) dependent enzymes. Forrow et al. does **not** disclose the use of both an electrode that functions as a counter electrode and a separate electrode that functions as a reference electrode. The third electrode disclosed by Forrow et al. functions as a fill indicator. The third electrode does **not** perform any function, i.e., the counter electrode function or the reference electrode function, in the determination of the concentration of the analyte in the sample. The fourth electrode disclosed by Forrow et al. functions as a dummy electrode, which indicates the degree of electrical interference in the measurement. The fourth electrode, i.e., the dummy electrode, does **not** perform the function of a counter electrode or a reference electrode. For these reasons, Forrow et al. does not anticipate claims 1-6 and 9-12.

Claims 14-27 were rejected under 35 U. S. C. §102(e) as being anticipated by Feldman et al. (US 6,592,745 B1). This rejection is respectfully traversed in view of the amendments to claim 14.

Feldman et al., U. S. Patent No. 6,592,745 B1 (hereinafter "Feldman et al."), discloses a sensor utilizing a non-leachable or diffusible redox mediator. The sensor includes a sample chamber to hold a sample in electrolytic contact with a working electrode. In at least some instances, the sensor contains a non-leachable or a diffusible second transfer agent. The sensor

and/or the methods used produce a sensor signal in response to the analyte that can be distinguished from a background signal caused by the mediator. The sensor can be used to determine the concentration of a biomolecule, such as glucose or lactate, in a biological fluid, such as blood or serum, using techniques such as coulometry, amperometry, and potentiometry. An enzyme capable of catalyzing the electrooxidation or electroreduction of the biomolecule is typically provided as a second electron transfer agent.

Feldman et al. discloses a biosensor having electrodes arranged in a facing arrangement. While the working electrode may comprise (i) a reagent responsive to an analyte in a sample of a biological liquid and (ii) an electron mediator deposited on an electrically conductive material, the characteristics of the reference electrode are unspecified. The working electrode of the biosensor strip of claims 14-27 of this application comprises (i) a reagent responsive to the analyte in the sample of the biological liquid and (ii) an electron mediator deposited on an electrically conductive material. Claims 14-27 of the present application specifies that the reference electrode of the biosensor strip comprises (i) a reagent responsive to the analyte in the sample of the biological liquid and (ii) an electron mediator deposited on an electrically conductive material. Thus, the disclosure of Feldman et al. fails to disclose the biosensor strip of the invention of claims 14-27 of this application. Accordingly, Feldman et al, fails to anticipate claims 14-27 of this application.

In view of the foregoing, it is submitted that claims 1-14, 16, and 18-27, as amended, are in condition for allowance, and official Notice of Allowance is respectfully requested.

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Respectfully submitted,
Shridhara Alva Karinka, et al.

Abbott Laboratories
D-377 AP6A-1
100 Abbott Park Road
Abbott Park, Illinois 60064-3500
Telephone: (847) 937-6182

David L. Weinstein
Registration No. 28, 128
Attorney for Applicants